The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARIANNE LANGSTON
and
HOOSHANG S. ZAVAREH

Appeal No. 2006-0881
Application No. 09/928,139

ON BRIEF

Before GARRIS, PAK, and JEFFREY T. SMITH, Administrative Patent Judges.

GARRIS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal which involves claims 1-8.

The subject matter on appeal relates to a process for obtaining single enantiomer *d-threo* methylphenidate or *l-threo*-methylphenidate, which comprises resolution of a mixture of these enantiomers and racemization of the unwanted enantiomer to give a mixture of all four stereoisomers, wherein the racemization comprises reacting the unwanted enantiomer with an

acid.[1] The resulting mixture is then treated whereby the *threo* stereoisomers are enriched over the *erythro* stereoisomers followed by separation of the *erythro* stereoisomers to leave a mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers for resolution. This appealed subject matter is adequately represented by independent claim 1 (the sole independent claim on appeal) which reads as follows:

1. A process for obtaining single enantiomer *d-threo*-methylphenidate or *l-threo*-methylphenidate, which comprises resolution of a mixture of the *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers; racemisation of the unwanted enantiomer, to give a mixture of all four stereoisomers, wherein the racemisation comprises reacting the unwanted enantiomer with an acid; enriching said mixture following racemisation wherein the *d-threo* and *l-threo* stereoisomers of methylphenidate are enriched over the *d-erythro* and *l-erythro* stereoisomers of methylphenidate; and separation of said *d-erythro* and *l-erythro* stereoisomers, to leave the said mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers for resolution.

The references set forth below are relied upon by the examiner in the § 103 and obviousness-type double patenting rejections before us on this appeal[2]:

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[1] According to the appellants, methylphenidate has two chiral centers, and any compound having two chiral centers will theoretically yield a racemate containing four separate isomers. The appellants further explain that it was known in the prior art to racemize methylphenidate wherein one of the two chiral centers became racemized to thereby yield two isomers (i.e., a mixture of the stereoisomers). However, it is the appellants' position that, prior to their invention, it was not known how to racemize both chiral centers of methylphenidate.

[2] In the answer, the examiner has referred to newly cited references (i.e., the Gao, Beausoleil, and Shimoju references; see pages 6 and 14 of the answer) as supporting her obviousness position even though these references are not included in the examiner's statements of her rejections. If these references are meant to support the proposition that compounds having two chiral centers are theoretically capable of being racemized to yield four isomers as indicated in the paragraph bridging pages 13-14 of the answer, then no such support is necessary particularly since the proposition has not been denied by the appellants (e.g., see the paragraph bridging pages 9 and 10 of the supplemental brief). On the other hand, if these newly cited references are relied upon for supporting the examiner's obviousness conclusions, then the references should have been positively included in the examiner's statements of her rejections. See In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970). Also see the Manual of Patent Examining Procedures (MPEP) § 706.02(j) (Rev. 3, August 2005) and § 2144.08 (id.).

Miller et al. (Miller '261)	4,254,261	Mar. 3, 1981
Zeitlin et al. (Zeitlin)	5,733,756	Mar. 31, 1998
Zavareh	6,121,453	Sep. 19, 2000
Harris et al. (Harris)	US 6,242,464 B1	June 5, 1002

Miller et al. (Miller), "Racemization of 6-oxo-2-piperidine-carboxylic acid enantiomers," Chemical Abstracts 94 :47148 (1981)

Armstrong et al. (Armstrong), "Separation of Drug Stereoisomers by the Formation of ß-Cyclodextrin Inclusion Complexes," Science, Vol. 232, pages 1132-1135 (1986)

Barry et al. (Barry), "Racemization of .alpha.-amino acid esters by aliphatic ketones in the presence of carboxylic acids," Chemical Abstracts 119:73084 (1993)

Claim 1 is rejected under 35 U.S.C.§ 112, first paragraph, "for lack of description and enablement" (answer, page 6).

Claims 1-6 and 8 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Zeitlin or Armstrong in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261.

Claims 1-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art referred to immediately above and further in view of Harris.

Finally, claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Zavareh '453 in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts, or Miller '261 and further in view of Harris.

(Footnote, continued)
Under these circumstances, it is appropriate to grant the appellants' request on page 6 of the reply brief that these newly cited references not be considered by the Board. It follows that we have not considered and will not further comment upon these newly cited references in our resolution of the subject appeal.

Rather than reiterate the respective positions advocated by the appellants and by the examiner concerning the above-noted rejections, we refer to the supplemental brief and reply brief as well as to the answer for a complete exposition thereof.

OPINION

For the reasons which follow, we cannot sustain any of the rejections advanced on this appeal.

Concerning her § 112 rejection of claim 1, the examiner states that "[t]he [claim 1] limitation of producing all four isomer[s] from the d- or l-threo finds no antecedent basis or enablement" (answer, page 6). Like the appellants, we find the examiner's exposition of this rejection to be less than a model of clarity with respect to why she considers claim 1 (but not the dependent claims) to violate the description and enablement requirements of § 112, first paragraph. The reasons for this lack of clarity are several. For example, the examiner's position is obfuscated by her comparison of appealed claim 1 with the disclosures of appellants' foreign priority documents. These foreign priority disclosures relate to § 119 benefits, not to the description and enablement issues raised by the rejection under review. In any event, for purposes of resolving these issues, we will consider this rejection to be founded upon the examiner's above-quoted criticism concerning the "limitation" of appealed claim 1.

There is no merit in the examiner's belief that the appellants' original disclosure of this application fails to contain written description of the claim 1 process for obtaining single enantiomer *d-threo* methylphenidate or *l-threo*-methylphenidate which comprises racemization of the unwanted enantiomer to give a mixture of all four stereoisomers. This subject matter of

appealed claim 1 was expressly recited in original claim 1 filed with the subject specification, and therefore the appellants' original disclosure would have conveyed with reasonable clarity to those skilled in the art that the appellants had possession on the application filing date of the subject matter in question. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). Also see MPEP § 2163 et. seq.

The examiner's enablement position also is not well-taken. For example, the disclosure on specification page 4 unquestionably enables the claim 1 process with respect to *d-threo*-methylphenidate. Moreover, as correctly indicated by the appellants, this claimed process is presumptively considered to be enabled with respect to *l-threo*-methylphenidate, and it is the examiner's initial burden to establish a reasonable basis to question enablement. See In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Also see MPEP § 2164 et. seq. On the record of this appeal, the examiner has failed to provide a reasonable explanation as to why the scope of protection provided by claim 1 is not adequately enabled by the appellants' disclosure. Id.

For the above stated reasons, we cannot sustain the examiner's § 112, first paragraph, rejection of claim 1.

Regarding her § 103 rejection of claims 1-6 and 8, the examiner finds that "Zeitline [sic] or Armstrong disclosed all the elements of the claims **except** wherein a recycled by racemization step was not included" but concludes "[i]t would have been prima facie obvious to employ a conventional modification of recycle/racemization step [i.e., see the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261] for the conventional process of Zeitline [sic] or

Armstrong **because** producing higher yields of a desirable single isomer is expected, and such expectation is the attributes taught by the prior art" (answer, page 10).

The examiner's obviousness conclusion is not supported by the here applied prior art. As more thoroughly detailed in the supplemental brief and reply brief, none of the secondary references applied by the examiner contain any teaching or suggestion of racemizing methylphenidate or any similar compound containing two chiral centers and thereby obtaining a mixture of all four stereoisomers (as required by the rejected claims) based upon a reasonable expectation of success. See In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (obviousness under § 103 requires a reasonable expectation of success).

It follows that the § 103 rejection of claims 1-6 and 8 as being unpatentable over Zeitlin or Armstrong in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261 cannot be sustained.

In discussing her § 103 rejection of claims 1-8, the examiner has made clear that the additionally applied Harris reference is relied upon solely for the limitation of dependent claim 7 (see pages 11 and 13 of the answer). Thus, as applied by the examiner, Harris fails to supply the above-discussed deficiencies of the other applied references. For this reason alone, we cannot sustained the examiner's § 103 rejection of claims 1-8 as being unpatentable over Zeitlin or Armstrong in view of the Miller Chemical Abstracts, the Barry Chemical abstracts or Miller '261 in view of Harris.[3]

[3] As an additional matter of concern regarding this rejection, we observe that the examiner has not even attempted to rebut the appellants' extensive explanation of why the Harris patent should be regarded as disqualified prior art under 35 U.S.C. § 103(c). It was inappropriate for the examiner and for her appeal conferees to have maintained to this rejection while failing to proffer any rebuttal whatsoever to the appellants' disqualification argument.

The examiner's obviousness position with respect to the obviousness-type double patenting rejection parallels her obviousness position with respect to the § 103 rejections. Thus, the former rejection is deficient for reasons previously explained with respect to the latter rejections. We also cannot sustain, therefore, the obviousness-type double patenting rejection of claims 1-8 as being unpatentable over claim 1 of Zavareh '453 in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261 in view of Harris.

In conclusion, we have not sustained any of the rejections advanced on this appeal because the examiner has failed to carry her initial burden of establishing a prima facie case of unpatentability with respect to each of these rejections. See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

ADDITIONAL MATTER

On page 6 of the supplemental brief, the appellants request "acknowledgement of Appellants' claim to foreign priority for both the GB 9602174.6 and GB 9618836.2 British applications under 35 U.S.C. § 119 in the subject '139 application."

The issue of foreign priority benefits is not relevant to any of the rejections before us in this appeal.[4] Therefore, the issue raised by the appellants' afore-quoted request is petitionable rather than appealable. See MPEP § 1201.

Under these circumstances, it would not be appropriate for this panel of the Board to entertain on the merits the request under consideration.

[4] For example, each of the references relied upon by the examiner in her rejections of the independent claim on appeal would be available as prior art regardless of whether the appellants' foreign priority claim is acknowledged or perfected.

SUMMARY

The decision of the examiner is reversed.

Bradley R. Garris)
Administrative Patent Judge)
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Chung K. Pak) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
)
Jeffrey T. Smith)
Administrative Patent Judge)

BRG/cam

Saliwanchik, Lloyd & Saliwanchik
A Professional Association
P. O. Box 142950
Gainesville, FL 32614-2950